

House Bill 885

GEORGIA LEGISLATION

By: Representatives Peake of the 141st, Watson of the 166th, Channell of the 120th, Kaiser of the 59th, Gravley of the 67th, and others

A BILL TO BE ENTITLED

AN ACT

1 To amend Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated,
2 relating to the use of cannabis for treatment of cancer and glaucoma, so as to provide for
3 continuing research into the benefits of medical cannabis to treat certain conditions; to
4 provide for a short title; to provide for legislative findings and intent; to provide for the
5 continuation of the Controlled Substances Therapeutic Research Program; to provide for
6 selection of academic medical centers to conduct the research; to provide for expansion of
7 the review board and its duties; to establish the responsibilities of academic medical centers;
8 to provide for the testing, storing, and dispensing by the Georgia Drugs and Narcotics
9 Agency; to provide for immunity; to provide for related matters; to repeal conflicting laws;
10 and for other purposes.

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

12 SECTION 1.

13 WHEREAS, the General Assembly finds and declares that clinical research has shown
14 certain benefits arising from the utilization of medical cannabis and, most recently,
15 significant benefits of a particular strain delivered orally for the treatment of seizure
16 disorders among children.

17 WHEREAS, nothing in this legislation should be construed as encouraging or sanctioning
18 the recreational use of cannabis, nor is this legislation to be construed as any intent of the
19 General Assembly to be moving in the direction of the legalization of recreational cannabis.

20 SECTION 2.

21 Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to the
22 use of cannabis for treatment of cancer and glaucoma, is amended by revising the article as
23 follows:

24 "ARTICLE 5

25 43-34-120.

26 This article shall be known and may be cited as the '~~Controlled Substances Therapeutic~~
27 ~~Research~~ Haleigh's Hope Act.'

28 43-34-121.

29 (a) The General Assembly finds and declares that ~~the potential medicinal value of~~
30 ~~marijuana has received insufficient study due to a lack of financial incentives for the~~
31 ~~undertaking of appropriate research by private drug manufacturing concerns. Individual~~
32 ~~physicians cannot feasibly utilize marijuana in clinical trials because of federal~~
33 ~~governmental controls which involve expensive, time-consuming approval and monitoring~~
34 ~~procedures this legislation's purpose is the compassionate potentially life-saving use of~~
35 medical cannabis and is not intended to sanction, encourage, or otherwise be construed as
36 a movement toward the legalization of recreational cannabis. Clinical research performed
37 over the past decades continues to show benefits arising from medical cannabis. Presently
38 there are in excess of one million United States medical cannabis patients and an increasing
39 number of physicians are recommending the therapeutic use of cannabis to their patients
40 in accordance with their respective state law. New extracts and compounds have been
41 developed demonstrating that cannabidiol, one of the most prevalent nonpsychoactive
42 cannabinoids, has significant health and wellness benefits as shown by recent publication
43 of the positive treatment of certain seizure disorders afflicting children.

44 (b) The General Assembly further finds and declares that ~~limited continuing~~ studies
45 throughout the nation indicate that ~~marijuana~~ cannabis and certain of its derivatives possess
46 valuable and, in some cases, unique therapeutic properties, including the ability to treat
47 cancer, as well as relieve nausea and vomiting which routinely accompany chemotherapy
48 and irradiation used to treat cancer patients. ~~Marijuana Cannabis~~ also may be effective in
49 treating, as well as reducing intraocular pressure in glaucoma patients ~~who do not respond~~
50 ~~well in adjunct~~ to conventional medications. Cannabis derivatives have recently shown to
51 be effective in the treatment of seizure disorders among other conditions and diseases.

52 (c) The General Assembly further finds and declares that, in enabling ~~individual~~
53 ~~physicians and their~~ patients to participate in a state-sponsored program for the
54 investigational use of ~~marijuana~~ cannabis and its derivatives, ~~qualified physicians and~~
55 ~~surgeons throughout the state~~ academic medical centers will be able to study the benefits
56 of the drug in a controlled clinical setting, and additional knowledge will be gained with
57 respect to dosage and effects.

58 (d) It is the intent of the General Assembly in enacting this article to permit research into
 59 the therapeutic and treatment applications of marijuana cannabis and its derivatives in
 60 cancer, and glaucoma, and seizure disorder patients. This would allow qualified physicians
 61 academic medical centers approved by the Patient Qualification Review Board created by
 62 Code Section 43-34-124 to provide authorize use of the drug on a compassionate basis to
 63 seriously ill persons suffering from cancer, as well as the severe side effects of
 64 chemotherapy or radiation treatment, and to persons suffering from glaucoma who are not
 65 responding to conventional treatment, and to persons suffering from seizure disorders,
 66 which persons would otherwise have no lawful access to it. It is the further intent of the
 67 General Assembly to facilitate clinical trials of marijuana cannabis and its derivatives,
 68 particularly with respect to persons suffering from cancer, and glaucoma, and seizure
 69 disorders who would be benefited by use of the drug.

70 (e) This article is limited to clinical trials and research into therapeutic applications of
 71 marijuana cannabis only for use in treating glaucoma, and in treating cancer and the side
 72 effects of chemotherapeutic agents and radiation, and utilizing medical cannabis for the
 73 treatment of seizure disorders and should not be construed as either encouraging or
 74 sanctioning the social use of cannabis marijuana. ~~Nothing in this article shall be construed~~
 75 ~~to encourage the use of marijuana in lieu of or in conjunction with other accepted medical~~
 76 ~~treatment, but only as an adjunct to such accepted medical treatment.~~

77 43-34-122.

78 As used in this article, the term:

79 (1) 'Academic medical center' means a research hospital that operates a medical
 80 residency program for physicians and conducts research that involves human subjects.

81 ~~(1)(2)~~ (2) 'Board' means the Georgia Composite Medical Board.

82 ~~(2)(3)~~ (3) 'Cannabis' 'Marijuana' means marijuana cannabis or tetrahydrocannabinol, as
 83 defined or listed in Article 2 of Chapter 13 of Title 16.

84 (4) 'Medical cannabis for the treatment of seizure disorders' means cannabis extracts and
 85 compounds of cannabis, including, but not limited to, those strains used to manufacture
 86 cannabidiol, a nonpsychoactive cannabinoid, that is delivered to the patient in a
 87 nonsmoking delivery system whether it be in the form of liquid, pill, vaporization, or
 88 injection or other delivery method that does not include smoking.

89 ~~(3)(5)~~ (5) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of
 90 this chapter.

91 ~~(4)(6)~~ (6) 'Program' means the Controlled Substances Therapeutic Research Program
 92 established pursuant to Code Section 43-34-123.

93 (5)(7) 'Review board' means the Patient Qualification Review Board established pursuant
94 to Code Section 43-34-124.

95 43-34-123.

96 (a) There is established under the Georgia Composite Medical Board the Controlled
97 Substances Therapeutic Research Program, which shall be administered by the board.
98 Under the program, the board shall act as a sponsor of state-wide investigational studies,
99 utilizing ~~as drug investigators individual physicians who elect~~ academic medical centers
100 selected by the board to participate in accordance with the guidelines and protocols
101 developed by the board. Such guidelines and protocols shall be designed to ensure that
102 stringent security and record-keeping requirements for research drugs are met and that
103 participants in the program meet those research standards necessary to establish empirical
104 bases for the evaluation of marijuana cannabis as a medically recognized therapeutic
105 substance. The board shall promulgate such rules and regulations as it deems necessary
106 or advisable to administer the program. In promulgating such guidelines, protocols, rules,
107 and regulations, the board ~~shall~~ may take into consideration those pertinent rules and
108 regulations promulgated by the ~~Federal~~ United States Drug Enforcement ~~Agency~~
109 Administration, the Food and Drug Administration, and the National Institute on Drug
110 Abuse.

111 (b) The program shall be limited to patients who are certified to the board by a ~~physician~~
112 selected academic medical center as being:

113 (1) Cancer patients involved in a life-threatening situation in which treatment by
114 chemotherapy or radiology has produced severe side effects; ~~or~~

115 (2) Glaucoma patients who are not responding to conventional controlled substances; or

116 (3) Seizure disorder patients.

117 (c) No patient may be admitted to the program without full disclosure by the ~~physician~~
118 academic medical center of the experimental nature of the program and of the possible
119 risks and side effects of the proposed treatment.

120 (d) The cost of any blood test required by the ~~federal~~ Food and Drug Administration prior
121 to entrance into the program shall be paid by the patient or through the program, donated
122 study funds, or funding seeking entrance into the program.

123 (e) Only the following persons shall have access to the names and other identifying
124 characteristics of patients in the program for whom marijuana cannabis has been prescribed
125 under this article:

126 (1) The board;

127 (2) The review board created by Code Section 43-34-124;

128 (3) The Attorney General or his or her designee;

- 129 (4) Any person directly connected with the program who has a legitimate need for the
130 information; and
131 (5) Any federal agency having responsibility for the program;
132 (6) Any academic medical center operating a program under this article; and
133 (7) Any patient program participant's attending physician.

134 43-34-124.

135 (a) The board shall appoint the Patient Qualification Review Board. Each member of the
136 review board shall be approved for such membership by a majority vote of the board and
137 shall serve at the pleasure of the board. The review board shall be composed of:

- 138 (1) A board certified physician in ophthalmology;
139 (2) A board certified physician in surgery;
140 (3) A board certified physician in internal medicine and medical oncology;
141 (4) A board certified physician in psychiatry;
142 (5) A board certified physician in radiology; and
143 (6) A pharmacist licensed under Chapter 4 of Title 26, relating to pharmacists, pharmacy,
144 and drugs;
145 (7) A board certified physician in pediatric neurology;
146 (8) A board certified physician in pain management; and
147 (9) A board certified pediatric epitologist.

148 (b) The review board shall elect from its members a chairperson and a vice chairperson.
149 The review board shall hold regular meetings at least once every 60 days and shall meet
150 at such additional times as shall be called by the chairperson of the review board or the
151 chairperson of the board. Each member of the review board shall receive for services for
152 each day's attendance upon meetings of such board the same amount authorized by law for
153 members of the General Assembly for attendance upon meetings of the General Assembly.
154 (c) The board shall adopt such rules and regulations as it deems necessary for the
155 performance of the duties of the review board.

156 ~~(d) The review board shall review all patient applicants for the program and their~~
157 ~~physicians and shall certify those qualified for participation in the program. The review~~
158 ~~board shall additionally certify pharmacies which are licensed by the state and which are~~
159 ~~otherwise qualified and certify physicians regarding the distribution of marijuana pursuant~~
160 ~~to Code Section 43-34-125. Meetings of the review board to certify patients, physicians,~~
161 ~~or pharmacies shall not be open to the public, as otherwise required by Chapter 14 of Title~~
162 50

- 163 (1) Shall review, evaluate, and rate applications for medical cannabis use programs
164 submitted by academic medical centers based on the procedures and guidelines
165 established by the board;
166 (2) Shall develop request applications for programs;
167 (3) Shall approve or deny applications for programs, approve or deny applications for
168 renewal of such programs, and monitor and oversee programs approved for operation
169 under this article;
170 (4) May rescind approval of a program if the board finds that the program is not in
171 compliance with the conditions of approval established by the board;
172 (5) Shall set application fees and renewal fees that cover its expenses in reviewing and
173 approving applications and providing oversight to programs; and
174 (6) May accept any gifts, donations, contributions, grants, bequests of funds or property,
175 or other funds.

176 43-34-125.

- 177 (a) The board An academic medical center operating a program approved under this article
178 shall apply to contract with the National Institute on Drug Abuse for receipt of marijuana
179 cannabis pursuant to this article and pursuant to regulations promulgated by the National
180 Institute on Drug Abuse, the Food and Drug Administration, and the Federal United States
181 Drug Enforcement Agency Administration or obtain such cannabis, cannabinoid, or any
182 other derivative, compound, or substantially similar products from any available source.
183 (b) The board shall cause marijuana approved for use in the program to be transferred to
184 a certified pharmacy, licensed by the state, for distribution to the certified patient by a
185 licensed pharmacist upon a written order for research medication of the certified physician,
186 pursuant to this article. Any reasonable costs incurred by the board in obtaining or testing
187 marijuana shall be charged to participating physicians who may seek reimbursement from
188 their research subjects utilizing the marijuana. Upon receipt of the research cannabis, its
189 extracts, compounds, or derivatives, or any other substantially similar product, the
190 academic medical center shall test the specifications of such product. Upon completion of
191 its testing of such product, the academic medical center shall notify the Georgia Drugs and
192 Narcotics Agency.
193 (c) Upon notification by the academic medical center, the Georgia Drugs and Narcotics
194 Agency shall take possession of the research product acquired under subsection (a) of this
195 Code section and retain such product until such time as the product shall be distributed by
196 the agency to the academic medical center.
197 (d) The Georgia Drugs and Narcotics Agency shall establish rules and regulations for the
198 storing and distributing of the research cannabis.

199 43-34-126.

200 Patient participants in the program are immune from state prosecution for possession of
201 marijuana as authorized by this article and under the program established in this article.
202 A person authorized under this program shall not possess an amount of marijuana in excess
203 of the amount prescribed under the authority of this article. The amount prescribed shall
204 be maintained in the container in which it was placed at the time the prescription was filled.
205 Physician, pharmacy, and pharmacist participants in the program are immune from state
206 prosecution for possession, distribution, and any other use of marijuana, which use is
207 authorized such persons by this article. Any such possession, distribution, or other use not
208 authorized by this article shall be enforced and punished as provided in Chapter 13 of Title
209 16, relating to controlled substances and dangerous drugs, and Chapter 4 of Title 26,
210 relating to pharmacists and pharmacies.

211 (a) The academic medical center operating a program approved under this article shall
212 report annually or more frequently as the board deems necessary to the board in a manner
213 specified by the board that includes the following:

214 (1) The number of patients served through the program and their county of residence;

215 (2) The conditions treated under the program; and

216 (3) Any outcome data on the results of the treatment through the program.

217 (b) An academic medical center operating a program approved under this article shall
218 apply annually to the board for renewal of approval of the program, in accordance with
219 procedures established by the board.

220 (c) An academic medical center operating a program under this article is subject to
221 inspection by the board to ensure that the program is operating according to the conditions
222 of approval established by the board.

223 43-34-127.

224 Any of the following persons acting in accordance with the provisions of this article shall
225 not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil
226 penalty or disciplinary action by a professional licensing board, or be denied any right or
227 privilege, for the medical use, prescription, administration, manufacture, or distribution of
228 medical cannabis:

229 (1) A patient enrolled in a program approved under this article who is in possession of
230 an amount of cannabis authorized under the program or such patient's caregiver, parent,
231 or guardian; or

232 (2) An academic medical center, an employee of an academic medical center, or any
233 other person associated with the operation of a program approved under this article for
234 activities conducted in accordance with the program approved under this article.

235 43-34-128.
236 A state employee is eligible for reimbursement for incurred counsel fees under Code
237 Section 45-12-26 in the event of a federal criminal investigation or prosecution solely
238 related to the employee's good faith discharge of public responsibilities under this article."

239 **SECTION 3.**

240 All laws and parts of laws in conflict with this Act are repealed.